Marc D. Youngelson, Esq.
COSNER YOUNGELSON
197 Route 18 South, Suite 104
East Brunswick, NJ 08816
Phone: (732) 937-8000 (Phone)
Facsimile: (732) 937-5439 (Facsimile)
marc@cosnerlaw.com

Of counsel:

Steven J. Moore, Esq.
James E. Nealon, Esq.
WITHERS BERGMAN LLP
1700 East Putnam Avenue
Greenwich, Connecticut 06830
Phone: (203) 302-4100
Fax: (203) 302-6611
Steven.moore@withersworldwide.com
James.nealon@withersworldwide.com

Attorneys for Plaintiffs Aurobindo Pharma Limited and Aurobindo Pharma Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA INC., Plaintiffs, v. ASTRAZENECA AB, ASTRAZENECA LP, and ASTRAZENECA PHARMACEUTICALS LP, Defendants.	Civil Action No. _____

COMPLAINT FOR DECLARATORY JUDGMENT

1. Plaintiffs Aurobindo Pharma Limited and Aurobindo Pharma Inc. (collectively, and individually, "Plaintiffs" or "Aurobindo"), by and through their undersigned counsel, hereby

bring their Complaint for Declaratory Judgment against Defendants AstraZeneca AB, AstraZeneca Pharmaceuticals LP, and AstraZeneca LP (collectively, and individually, "Defendants" or "AstraZeneca") under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the provision of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act ("FDCA") establishing civil actions for patent certainty, 21 U.S.C. § 355(j)(5)(C), that U.S. Patent Nos. 6,403,616 ("the '616 patent") and 6,428,810 ("the '810 patent") are not infringed by Aurobindo, or invalid, so that the U.S. Food & Drug Administration ("FDA") can provide Aurobindo final approval to market its omeprazole magnesium delayed release tablets OTC Tablets, eq. 20 mg base, which are generic equivalents of Defendant's Prilosec (omeprazole magnesium) OTC® drug product, such that its generic product may be marketed at the earliest possible date under the applicable statutory and FDA regulatory provisions to allow the public to enjoy the benefits of generic competition for these products.

2. Because Defendants did not assert U.S. Patent Nos. 6,403,616 ("the '616 patent") and 6,438,810 ("the '810 patent") which were said to be invalid or not infringed by Aurobindo in its notice letter pertaining to its ANDA 206877 ("Aurobindo's Notice Letter"), two-(2) patents that are listed in the Orange Book at the NDA for Prilosec OTC (omeprazole magnesium) delayed release tablets, eq. 20 mg base, within 45 days of receipt of Aurobindo's Notice Letter, Plaintiffs are statutorily entitled pursuant to 21 U.S.C. § 355(j)(5)(C) to file and maintain a declaratory judgment action against Defendants under 28 U.S.C. §§ 2201 and 2202 to obtain a declaration that the manufacture, use, offer-for-sale, sale, and/or importation into the United States of Plaintiffs' ANDA 206877 for omeprazole magnesium delayed-release tablets (OTC), eq. 20 mg base, will not infringe any valid and enforceable claim of these patents.

3. Plaintiffs further allege:

PARTIES

4. Plaintiff Aurobindo Pharma Limited is an Indian corporation, having its principal place of business office at Maitri Vihar, Plot #2, Ameerpet, Hyderabad-500038, Telangana, India.

5. Plaintiff Aurobindo Pharma Inc. is a corporation and existing under the laws of the state of Delaware, having its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810.

6. Upon information and belief, Defendant AstraZeneca AB purports to be a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden. Upon information and belief, Astra AKTIEBOLAG, a predecessor company of AstraZeneca AB, has assigned all of its rights to the patents-in-suit to AstraZeneca AB.

7. Upon information and belief, Defendant AstraZeneca LP is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803, and is the U.S. subsidiary of AstraZeneca PLC. Upon information and belief, AstraZeneca LP is authorized to do business in New Jersey, with a registered agent for service of process located at The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, New Jersey 08628.

8. Upon information and belief, Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850, and is the applicant on NDA No. 021229 for Prilosec OTC, Omeprazole Magnesium delayed release oral tablets, eq. 20 mg base. Upon information and belief, AstraZeneca Pharmaceuticals LP is authorized to do business in

New Jersey, with a registered agent for service of process located at The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, New Jersey 08628.

JURISDICTION AND VENUE

9. This is a declaratory judgment action brought under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., the FDCA, 21 U.S.C. § 301 *et seq*. (as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C § 355)), the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10. Subject matter jurisdiction exists under 28 U.S.C. § 1331 and 1338(a). This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

11. Personal jurisdiction as to Defendants is proper in this district because it has consented to personal jurisdiction by filing numerous cases in this district, including *AstraZeneca et al. v. Perrigo Co, et al.* Civil Action No. 3:15-cv-01057-MLC-TJB; *Astrazeneca AB et al. v. Lupin Ltd, et. al*., 3:15-cv-06902-MLC-TJB; *Astrazeneca AB et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, 3:14-cv-04782-MLC-TB;and *Astrazeneca AB et al. v. HEC Pharm Co., LTD. et al*, 3:15-cv-06025-MLC-TJB, the latter three (3) of which involve Defendants filing declaratory judgment counterclaims on one of the patents involved in this suit, the ‘810 patent, and each of which has cited failure by the applicable defendants to sue within 45 days after receipt of their respective notice letters (involving the S-isomer of omeprazole, that is, esomeprazole, in the form of either esomeprazole magnesium dihydrate delayed release capsules 20 mg (OTC), the equivalent of the drug Nexium 24HR OTC or esomeprazole magnesium

delayed-release tablets 20mg and 40mg (Rx), the equivalent of the drug NEXIUM esomeprazole magnesium delayed-release tablets, 20 mg and 40 mg (Rx)).

12. Upon information and belief, the Court also has personal jurisdiction over the Defendants due to them availing themselves of the rights and privileges of this forum, because Defendants conduct substantial business in, and have regular systematic contact with, this District including through marketing and sales of its Prilosec OTC product and other pharmaceutical products, deriving substantial revenue from sale of its products in this district.

13. Venue is proper in pursuant to 28 U.S.C. §§ 1391 and 1400(b).

PATENTS-IN-SUIT

14. According to the electronic records of the United States Patent & Trademark Office (PTO), U.S. Patent No. 6,428,810 ("the '810 patent"), entitled "Pharmaceutical Formulation Comprising Omeprazole," issued on or about August 6, 2002, to inventors Pontus Bergstrand and Peter Wang, and has been assigned to Defendant AstraZeneca AB through Astra Aktiebolag.

15. According to the PTO's electronic records, U.S. Patent No. 6,403,616 ("the '616 patent"), entitled "Chemical Process and Pharmaceutical Formulation," issued on or about June 11, 2002, to inventors Magnus Erickson, Anders Gustavsson, and Lars Josefsson, and has been assigned to Astrazeneca AB by Astra Aktiebolag.

FACTS COMMON TO ALL COUNTS

A. FDA Approval of New Brand-Name Drugs

16. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the Medicare Prescription Drug,

Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"), sets forth the rules that the U.S. Food and Drug Administration ("FDA") follows when considering whether to approve both brand-name and generic drugs.

17. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

18. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted. *See* 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b), (c)(2).

19. Upon the FDA's approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

B. Generic Competition – Abbreviated New Drug Applications (ANDAs).

20. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA to simply the procedure for the obtaining of approval for generic drugs. The purpose of the act was to decrease the cost of pharmaceuticals by increasing competition.

21. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

22. To receive approval of its ANDA, an applicant must, *inter alia*, show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

23. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must also "certify" that any patent information properly listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

24. When seeking FDA approval to market prior to expiration of patents listed in the Orange Book, an ANDA applicant must submit a so-called "paragraph IV" certification asserting that the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The ANDA holder filing such paragraph IV certifications must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B).

25. If the patent holder brings suit within 45 days of receiving the paragraph IV certification notice required by 21 U.S.C. § 355(j)(2)(B), the FDA cannot give final approval to the ANDA for 30 months, unless the district court enters an order shortening that period or, if the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity) before expiration of such 30 month period. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

C. First-to-File ANDA Applicant's 180-day Generic Market Exclusivity

26. If an ANDA applicant is the "first-to-file" a substantially complete ANDA with a paragraph IV certification to an Orange Book-listed patent and provides appropriate notice to the FDA, the NDA holder, and all patent owner(s) for a particular generic product, that first-to-file ANDA applicant may be awarded a 180-day period of marketing exclusivity against other companies that subsequently file ANDAs referencing the same branded drug product. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

27. An ANDA with a paragraph IV certification shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug by any first-to-file ANDA applicant. See 21 U.S.C. §355(j)(5)(B)(iv)(I).

D. Medicare Modernization Act of 2003 and Forfeiture of 180-Day Exclusivity

28. In December 2003, Congress passed the Medicare Modernization Act of 2003 ("MMA"). Title XI of the MMA entitled "Access to Affordable Pharmaceuticals," includes a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement of an "Orange Book" listed patent if the NDA holder does not sue within 45 days of receiving notice of a Paragraph IV certification and an offer of confidential access to the ANDA application was made. 21 U.S.C. § 355(j)(5)(C).

29. The MMA also added forfeiture provisions for the 180-day exclusivity to which a first generic ANDA filer might otherwise be entitled pursuant to the Hatch Waxman Act. (*See* 21 U.S.C. §355 (j)(5)(D)). Under one of these forfeiture provisions (*see* 21 U.S.C. § 355(j)(5)(D)(i)(I)), the first-to-file ANDA applicant can forfeit its 180-day marketing exclusivity period if the ANDA is not marketed within 75 days after a final and non-appealable court decision finding an Orange Book listed patent invalid or not infringed in an infringement or declaratory judgment action, wherein such declaratory judgment action was brought by either a first-to-file ANDA applicant or any other ANDA applicant, and such action relates to the Orange Book listed patent for which the ANDA applicant submitted and lawfully maintained a paragraph IV certification.

E. Prilosec OTC Omeprazole Magnesium Delayed-Release Tablets

30. Upon information and belief, Defendant AstraZeneca Pharmaceuticals is the holder of NDA No. 021229 for Prilosec OTC Omeprazole Magnesium Delayed-Release Tablets, 20 mg.

31. Upon information and belief, Defendants submitted information on U.S. Patent Nos. 5,817,338, 5,900,424, 6,403,616, and 6,428,810 to FDA for listing in the Orange Book. By virtue of that submission, FDA listed each of these patents in the Orange Book in connection

with the approved NDA for Prilosec OTC omeprazole magnesium delayed-release tablets, eq. 20 mg base.

32. U.S. Patent No. 5,817,338 expired on October 6, 2015, and U.S. Patent No. 5,900,424 expired on May 4, 2016. U.S. Patent No. 6,403,616 and 6,428,810 are set to expire, respectively, on November 15, 2019 and November 3, 2019.

F. The First Paragraph IV Filer Challenging Orange Book Patents Listed in Respect of Prilosec OTC Omeprazole Magnesium Delayed-Release Tablets, 20 mg, and the Need to Provoke Forfeiture For Others to Get Onto The Market

33. Upon information and belief, Perrigo R& D Company, an abbreviated name for of Perrigo Research and Development Company (collectively "Perrigo"), was the first filer of an ANDA challenging patents listed in the Orange Book for NDA No. 021229 for Prilosec OTC Omeprazole Magnesium Delayed-Release Tablets, eq. 20 mg base. Perrigo is thus entitled to 180 days of exclusivity starting from its marketing of the drug in the United States. Perrigo R&D Company is a subsidiary of L. Perrigo, a corporation organized under the laws of the State of Michigan having a place of business at 71 Suttons Lane, Piscataway, New Jersey 08854 and currently conducts business in New Jersey. Upon information and belief, Perrigo -- through ANDA No. 204152 -- is the only company that has received final approval for omeprazole magnesium delayed release tablets (OTC), eq. 20 mg base.

34. Upon information and belief, Perrigo has parked its exclusivity on omeprazole magnesium delayed release tablets (OTC), eq. 20 mg base, *inter alia*, by failing to market the drug after receiving final approval from the FDA on July 30, 2015 (Exhibit A), thus effectively blocking other generic competitors from getting to the market, unless through a declaratory judgment a competitor can cause a forfeiture of Perrigo's 180 day exclusivity, as Plaintiff seeks to do in this action.

35. Upon information and belief, Perrigo continues to sell a competitive product obtained through a deal with Dexcel Pharma Technologies, Ltd. ("Dexcel"), an Israeli company that obtained the right to market omeprazole base in 20 mg tablets OTC through its NDA No. 022032 (approved Dec. 4, 2007), via a 505(b)(2) FDA filing. On information and belief, Perrigo announced its association with Dexcel for a generic version of Prilosec OTC in June of 2006.

36. Upon information and belief, under this agreement, Perrigo is the exclusive marketer and distributor of the OTC product in the United States, and each company shares in the costs and potential benefits associated with the commercialization of the product. Such product, on information and belief, has been a large product in Perrigo's drug portfolio.

37. Upon information and belief, Perrigo has little incentive to go to market with a competitive Omeprazole Magnesium Delayed-Release Tablets, eq. 20 mg base, given its sales of Omeprazole Base Delayed-Release Tablets (OTC), 20 mg pursuant to its deal with Dexcel.

38. Upon information and belief, the only other competitor on the U.S. omeprazole OTC market is Dr. Reddy's Labs Ltd. ("Dr. Reddy's"), which received the right to market omeprazole magnesium capsules, delayed release, eq. 20 mg base under ANDA No. 078878, which was approved on June 5, 2009. Upon information and belief, Dr. Reddy's launched its capsule product in 2010.

G. Plaintiffs ANDA No. 206877 for Omeprazole Magnesium Delayed-Release Tablets OTC. Eq. 20 mg Base

39. Plaintiffs filed an ANDA with the FDA seeking approval for omeprazole magnesium delayed-release tablets (OTC), eq. 20 mg base. FDA assigned Plaintiffs' ANDA No. 206877 ("ANDA No. 206877").

40. Plaintiffs' ANDA No. 206877 references AstraZeneca LP's NDA No. 021229.

41. Because Plaintiffs' ANDA No. 206877 seeks FDA approval to market omeprazole magnesium delayed-release tablets (OTC), eq. 20 mg base, before expiration of the '616, and '810 patents listed in the Orange Book, Plaintiffs' ANDA No. 206877 includes a paragraph IV certification for the '616, and '810 patents (as it did to the two other patents that have since expired).

42. In accordance with 21 U.S.C. § 355(j)(2)(B), notice was provided to, *inter alia*, Defendants that ANDA No. 206877 was submitted to FDA with a paragraph IV certification to the '616, and '810 patents (as well as the other two patents that have since expired). This notice, sent on December 22, 2014, included a detailed statement setting forth factual and legal bases as to why the '616 and '810 patent claims will not be infringed by the manufacture, use, offer for sale, sale, or importation of omeprazole magnesium delayed-release tablets (OTC), eq. 20 mg base, described in Plaintiffs' ANDA ("Proposed ANDA Product"). The notice detailed why the '810 patent is invalid, and, *inter alia*, expressly reserved the right to raise additional defenses including non-infringement, invalidity, and unenforceability in the event that suit was filed on the patents for which a paragraph IV certification was made, including the '616 and '810 patent, the only patents in the Orange Book which have not already expired.

43. The omeprazole magnesium delayed-release tablets (OTC), eq. 20 mg, base, described in Plaintiffs' ANDA No. 206877 does not infringe any valid or enforceable claim of the '616 or '810 patent, for reasons set forth in Plaintiffs' paragraph IV certification detailed statement.

44. Following receipt of notice of paragraph IV certification to the '616 and '810 patents, Defendants did not sue Plaintiffs for infringement within 45 days following receipt of Plaintiffs' notices of Paragraph IV certification.

45. Defendants have refused thereafter to grant Plaintiffs a covenant not to sue for infringement of the ‘616 and ‘810 patent.

46. Defendants’ actions, including their refusal to grant Plaintiffs a covenant not to sue for infringement of the ‘616 and ‘810 patents, and Plaintiffs’ paragraph IV certifications as to these patents, have created a controversy between Plaintiffs and Defendants as to infringement of the ‘616 and ‘810 patents.

47. The ‘616 and ‘810 patents remain listed in the Orange Book with respect to OTC NDA No. 021229, and Defendants maintain and continue to represent to the public that the respective patents claim the drug approved in OTC NDA No. 021229 or a method of using that drug, and that a claim of patent infringement could reasonably be asserted against any unlicensed ANDA applicant who attempts to market a generic version of the drug prior to the delisting of these patents.

48. On June 16, 2016 Plaintiffs received tentative approval from the FDA (Exhibit B) for the Proposed ANDA product in Plaintiffs' ANDA No. 206877. However, final approval cannot be obtained from the FDA until Plaintiffs obtain a judgment from this Court that the Proposed ANDA Product does not infringe any valid claims of the two patents that remained in force as of its tentative approval date, that is, the ‘616 and ‘810 patents.

49. Plaintiff Aurobindo desires to bring its generic Prilosec OTC delayed-release tablets (OTC), eq. 20 mg base, to the market at the earliest, to allow the public to enjoy the benefit of generic competition for this product at the earliest possible date under the applicable statutory and FDA regulatory provisions.

50. Upon information and belief, Defendants’ listing of the ‘616 and ‘810 patents in the Orange Book for NDA No. 021229, and the associated 180-day exclusivity held by Perrigo as the first-to-file ANDA applicant, are the only obstacles preventing the FDA from granting

Plaintiffs final approval of ANDA No. 206877, which would permit Plaintiffs to begin marketing the Proposed ANDA Product as a generic equivalent to Prilosec OTC, omeprazole magnesium delayed-release tablets (OTC), eq. 20 mg base.

51. As there are no other unexpired patents other than the '616 and '810 patents, or other exclusivities listed in the Orange Book for NDA No. 021229, had Defendants not listed the '616 and '810 patents in the Orange Book for NDA No. 021229, there would be no 180-day exclusivity at present for Perrigo as the first-to-file ANDA applicant.

52. By listing the '616 and '810 patent in the Orange Book for NDA No. 021229, Plaintiffs are caused and are responsible for the current existence of 180-day exclusivity period for Perrigo, the first-to-file ANDA applicant.

53. Plaintiffs may market its Proposed ANDA No. 207877 product before the expiration of the 180-day exclusivity held by Perrigo, as the first-to-file ANDA applicant, if that exclusivity period is forfeited by a triggering event defined by 21 U.S.C. § 355(j)(5)(D)(i)(I), including a final court decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the '616 patent and the '810 patent are not infringed, and failure of Perrigo to market expeditiously.

54. If the 180-day exclusivity held by Perrigo, as the first-to-file ANDA applicant, is not forfeited or otherwise extinguished, then that exclusivity period will continue to prevent Plaintiffs from marketing its Proposed ANDA No. 206877 Product until the latter of the '616 patent and the '810 patent expire (November 15, 2019 in respect of the '616 patent).

H. The '616 Patent

55. The '616 patent, issued by the PTO on June 11, 2002, is entitled "Pharmaceutical Process and Pharmaceutical Formulation" and, on its face, lists Defendant AstraZeneca AB as the assignee. The PTO's assignment records reflect that AstraZeneca AB

received assignment of the application leading to the ‘616 Patent from Astra Aktiebolag, the entity to which all the named inventors on the patent assigned their rights. (A true and correct copy of the ‘616 Patent is attached hereto as Exhibit C).

56. The ‘616 states that it relates “to an improved process for the manufacturing of an alkaline salt of an acid susceptible proton pump inhibitor compound, such as a substituted sulphinyl heterocyclic compound containing an imidazole moiety. 1:6-13.

57. Claim 1 of the ‘616 patent is the only independent claim, with each of claims 2-18 ultimately depending therefrom.

58. Plaintiffs set forth in the detailed statement of their notice letter to Defendants reasons why Plaintiffs' process for manufacturing omeprazole magnesium does not infringe upon any of the claims of the ‘616 patent.

59. Sole independent claim 1, and thereby all claims of the patent (as the remainder of the claims ultimately depend on claim 1), require a washing step of the prepared alkaline salt of the substituted sulphinyl compound of Formula I in the ‘616 patent to be washed with a basic aqueous solvent mixture.

60. As part of its manufacturing process, Plaintiffs do not employ a washing step in which the prepared alkaline salt of the substituted sulphinyl compound of Formula I in the ‘616 patent is washed with a basic aqueous solvent mixture.

61. Defendants were informed by Plaintiffs in their Notice Letter that Plaintiff’s process did not employ a washing step of the prepared alkaline salt of the substituted sulphinyl compound of Formula I in the ‘616 patent to be washed with a basic aqueous solvent mixture, and, as such, Plaintiffs’ process did not infringe any of the claims of the ‘616 patent.

62. Defendants did not sue Plaintiffs for infringement of the ‘616 patent within 45 days after receipt of Plaintiffs’ Notice Letter notifying Plaintiffs had submitted ANDA No.

206877 to the FDA seeking approval for omeprazole magnesium, delayed-release tablets (OTC), eq. 20 mg base, prior to the expiration of the '616 patent.

63. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc), the Notice Letter contained an Offer of Confidential Access, as defined by 21 U.S.C. § 355(j)(5)(C)(i)(III). Thus Defendants had the right to review the process of Plaintiffs to assure non-infringement.

64. Under the framework of the Hatch-Waxman Amendments, Plaintiffs are restrained from selling a non-infringing product because of Defendants action of listing the '616 patent in the Orange Book delays FDA final approval of Plaintiffs' ANDA and excludes Plaintiffs form the market.

65. Defendants' listing of the '616 patent creates an independent barrier to the drug market that deprives Plaintiffs of an opportunity to compete with a non-infringing product.

66. A final and non-appealable court decision relating to Plaintiffs' non-infringement of any valid claim of the '616 patent would ensure that Plaintiffs are able to obtain final approval of its ANDA No. 206877 before the expiration of the '616 patent as long as the first-to-file non-forfeiting ANDA applicant does not launch before the expiration of the '616 patent and its 180 day exclusivity straddles the expiration date of the '616 patent.

67. The first-to-file ANDA applicant is Perrigo.

68. On information and belief, Perrigo is also the first ANDA applicant to challenge the '616 Patent via a Paragraph IV certification.

69. A final court decision that proposed product under Plaintiffs' ANDA No. 206877 does not infringe any valid claim of the '616 Patent, in conjunction with a similar final court decision in relation to the '810 Patent, would operate as a potential forfeiture event of the first-to-file ANDA applicant's 180-day marketing exclusivity under 21 U.S.C. §355(j)(5)(D)(i)(I)

(bb)(AA)) should the first-to-file ANDA applicant not be able to market within 75 days of such final non-appealable court decision.

70. For all the foregoing reasons, a real, actual and justiciable controversy exists between Plaintiffs on the one hand, and Defendants on the other hand, regarding Plaintiffs' non-infringement of the '616 Patent, constituting a case of actual controversy to ensure that Plaintiffs' Proposed ANDA Product can freely enter the market earlier than it would absent a final and non-appealable order relating to the '616 Patent. This controversy regarding patent certainty is defined 21 U.S.C. §355(j)(5)(C)(i)(II) and is within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

I. The '810 Patent

71. The '810 patent was issued by the PTO on July 18, 2002 and is entitled "Pharmaceutical Composition Comprising Omeprazole" and lists Defendant AstraZeneca AB as the assignee. The assignment record of the USPTO shows AstraZeneca AB having received assignment of the application leading to the '810 patent from Astra Aktiebolag, the entity to which all the named inventors on the patent assigned their rights.

72. A true and correct copy of the '810 Patent is attached hereto as Exhibit D.

73. The '810 Patent states that it relates to an omeprazole containing formulation comprising a core material that comprises the active ingredient containing omeprazole "and optionally an alkaline reacting compound, the active ingredient in admixture with a pharmaceutically acceptable excipient, such as for instance a binding agent, and on said core material a separating layer and an enteric coating letter. A hydroxypropyl cellulose (HPC) with a specific cloud point is used in the manufacture of the claimed pharmaceutical formulations." *Abstract*.

74. Claim 1 of the ‘810 Patent is the only independent claim, with each of claims 2-21 ultimately depending therefrom.

75. Plaintiffs set forth in the detailed statement of their notice letter to Defendants reasons why their process for manufacturing omeprazole magnesium tablets does not infringe upon any valid claim of the ‘810 Patent.

76. Sole independent claim 1, and thereby all claims of the patent (as the remainder of the claims ultimately depend on claim 1), require the separating layer comprises a hydroxypropyl cellulose (HPC) with a cloud point of at least 38^{o} C.

77. The patent specification does not disclose any technical instruction on the making the HPC to be used in the claimed formulations.

78. The cloud point is a test for pure compounds, and thus could not be determined in the separating layer comprising HPC.

79. The ‘810 patent provides no information on the chain length, branching, alternate substitutions, hydroxypropylation degree, or hydroxypropylation distribution of the HPC within the separating layer.

80. The specification of the '810 Patent provides no direction as to how to make the separating layer.

81. The specification of the patent provides no direction as to what compounds may be included in the separation layer.

82. The specification provides only three-(3) working examples.

83. Neither the specification or file history provide any examples of use of HPC in a separation layer having a cloud point of 43^{o}C of higher.

84. Claims 1- 12 of the ‘810 Patent are invalid for lack of enablement under 35 U.S.C. §§1 and 112.

85. The claims are of the ‘810 Patent are invalid for the failure of ‘810 Patent specification to enable the full scope of the claims.

86. The claims are also invalid for failure in the written description.

87. For this and other reasons set forth in its notice letter, the '810 Patent lacks enablement and written description.

88. Plaintiffs also asserted in their notice letter that the claims 1-3, 5, 6, 9-17, 19 and 20 of the ‘810 were anticipated by prior art, and that all claims were obvious over certain prior art references.

89. The recited anticipating prior art includes all of elements of each of claims 1-3, 5, 6, 9-17, 19 and 20 other than it makes no recitation of the cloud point.

90. However, the separating layer of the embodiment recited in Plaintiffs' notice letter in regard to the asserted anticipating prior art comprises hydroxypropyl cellulose with a cloud point of at least 38^{o}C.

91. In fact the separating layer of the embodiment recited in Plaintiffs' notice letter in regard to the asserted anticipating prior art comprises hydroxypropyl cellulose with a cloud point of at least 40^{o}C.

92. Moreso, the separating layer of the embodiment recited in Plaintiffs' notice letter in regard to the asserted anticipating prior art comprises hydroxypropyl cellulose with a cloud point of at least 41^{o}C.

93. Plaintiffs also asserted in their notice letter that the ‘810 Patent is obvious over prior art.

94. The prior art noted in Plaintiffs' notice letter make obvious all claims of the ‘810 Patent.

95. Furthermore, Plaintiffs alternatively (if not anticipating) asserted that its recited anticipating prior art makes obvious claim 1 of the '810 Patent.

96. It would have been obvious to modify the art asserted by Plaintiff to be anticipating to include the features recited in the claims 1 – 22 of the ‘810 patent to improve the stability of the solid drug.

97. In terms of claims 7, 8, 21 and 22, Plaintiffs asserted that these claims were obvious as well.

98. Claims 1 -22 of the ‘810 patent are at the very least are obvious in light of the references cited by Plaintiffs to be anticipating in view of the other prior art reference recited in its notice letter.

99. Defendants did not sue Plaintiffs for infringement of the ‘810 patent within 45 days after receipt of Plaintiffs Notice Letter notifying Plaintiffs had submitted ANDA No. 206877 to the FDA seeking approval for omeprazole magnesium, delayed-release tablets (OTC), eq. 20 mg base, prior to expiration of the ‘810 patent, after reviewing Plaintiffs’ positions on non-infringement/invalidity set forth in its Detailed Statement (forming part of the notice letter).

100. Upon information and belief, Plaintiffs did not sue others who have asserted invalidity and non-infringement of such patent, including Lupin Ltd. in *Astrazeneca AB et al. v. Lupin Ltd, et al*., 3:15-cv-06902-MLC-TJB (counterclaim of non-infringement and invalidity of ‘810 patent by Lupin); Zydus Pharmaceuticals (USA) Inc. et al. in *Astrazeneca AB et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, 3:14-cv-04782-MLC-TB (counterclaim of invalidity of ‘810 patent by Zydus); HEC Pharm. Co. LTD in *Astrazeneca AB et al. v. HEC Pharm Co., LTD. et al*, 3:15-cv-06025-MLC-TJB (counterclaim of non-infringement and invalidity of ‘810 patent by HEC Pharm Co. LTD), and Perrigo after it filed its notice letter in respect of omeprazole magnesium, extended-release tablets (OTC), eq. 20 mg base.

101. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc), the Plaintiffs' Notice Letter contained an Offer of Confidential Access, as defined by 21 U.S.C. § 355(j)(5)(C)(i)(III).

102. Under the framework of the Hatch-Waxman Amendments, Plaintiffs are restrained from selling a non-infringing product because of Defendants action of listing the '810 patent in the Orange Book delays FDA final approval of Plaintiffs' ANDA and excludes Plaintiffs from the market.

103. Defendants listing of the '810 Patent creates an independent barrier to the drug market that deprives Plaintiffs of an opportunity to compete with a non-infringing product.

104. With a concomitant final and non-appealable court decision relating to Plaintiffs' non-infringement of any valid claim of the '616 Patent, a final and non-appealable court decision relating to Plaintiffs' non-infringement of any valid claim of the '810 Patent would ensure that Plaintiffs are able to obtain final approval of its ANDA No. 206877 before the expiration of the '810 Patent absent an expeditious launch by the first-to-file ANDA applicant.

105. Upon information and belief, Perrigo is the first ANDA applicant to challenge the '810 patent via a Paragraph IV certification.

106. Perrigo as the first ANDA applicant to challenge the '810 patent via a Paragraph IV certification was not sued.

107. A final court decision that proposed product under Plaintiffs' ANDA No. 206877 does not infringe any valid claim of the '616 patent, in conjunction with a similar final court decision in relation to the '810 patent, would operate as a forfeiture event of the first-to-file ANDA applicant's 180-day marketing exclusivity under 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(AA)) should Perrigo not expeditiously go to the market.

108. A real, actual and justiciable controversy exists between Plaintiffs on the one hand, and Defendants on the other hand, regarding Plaintiffs non-infringement of the '810 patent,

constituting a case of actual controversy to ensure that Plaintiffs' Proposed ANDA Product can freely enter the market earlier than it would absent a final and non-appealable order relating to the '810 patent. This controversy regarding patent certainty is defined 21 U.S.C. §355(j)(5)(C)(i)(II) and is within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

FIRST COUNT: Declaration of Non-Infringement of the '616 Patent

109. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 108 herein as fully as if set forth herein.

110. A present, genuine, and justiciable controversy exists between Plaintiffs and Defendants concerning, *inter alia*, the issue of whether Plaintiffs' manufacture, use, offer for sale, or sale of the omeprazole magnesium delayed-release tablets (OTC), eq. 20 mg base, described in Plaintiffs' ANDA No. 206877 would infringe any valid or enforceable claim of the '616 Patent.

111. Plaintiffs are entitled to a declaratory judgment that the manufacture, use, offer for sale, or sale of the omeprazole magnesium delayed-release tablets (OTC), eq. 20 mg base, described in Plaintiffs' ANDA No. 206877 would not infringe any valid or enforceable claim of the '616 patent.

SECOND COUNT: Declaration of Invalidity of the '810 Patent, and Therefore Non-Infringement of Any Valid Claim.

112. Plaintiffs re-allege and incorporate by reference the allegations of the preceding paragraphs 1-111.

113. A present, genuine, and justiciable controversy exists between Plaintiffs and Defendants regarding, *inter alia*, the validity of the '810 Patent.

114. Plaintiffs are entitled to a declaration that the ‘810 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the entry of judgment in their favor and against Defendants as follows:

(a) declaring that Plaintiffs’ submission of ANDA No. 206877 does not infringe any valid claim of the ‘616 and ‘810 Patents;

(b) declaring that Plaintiffs’ manufacture, use, sale, offer for sale, or importation of the omeprazole magnesium delayed-release tablet (OTC), eq. 20 mg base, that is the subject of ANDA No. 206877 does not infringe, directly or indirectly, either literally or under the doctrine of equivalents, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘616 Patent;

(c) declaring that Plaintiffs’ manufacture, use, sale, offer for sale, or importation of the omeprazole magnesium delayed-release tablet (OTC), eq. 20 mg base that is the subject of ANDA No. 206877 would not, if marketed, infringe any valid and/or enforceable claim of the ‘810 Patent;

(d) declaring that there is an actual and justiciable controversy between the parties concerning whether Plaintiffs' manufacture, use, offering for sale or importation of the omeprazole magnesium delayed-release tablet (OTC), eq. 20 mg base that is the subject of ANDA No. 206877 will infringe either of the ‘616 or ‘810 patents;

(e) declaring that the Food & Drug Administration may finally approve Plaintiffs’ omeprazole magnesium delayed-release tablet (OTC), eq. 20 mg base, that is the subject of ANDA No. 206877 whenever the application is otherwise in condition for approval, without waiting any further order, judgment or decree of this Court;

(d) declaring that the judgment entered in this case is a judgment reflecting a decision that no valid claims of the patents-in-suit are infringed pursuant to 21 U.S.C. 355(j)(5)(B)(iii)(I)(aa), and that any exclusivity periods to which Defendants might otherwise be entitled (including any pediatric exclusivity) concerning the ‘616 and ‘810 patents are shortened to expire upon the date of entry of judgment in this action;

(e) entering a final judgment under Fed. R. Civ. P. 58 that Plaintiffs’ ANDA No. 206877 products will not infringe any valid claim of either the ‘616 or ‘810 Patents;

(f) entering a final judgment under Fed. R. Civ. P. 58 that the '810 Patent cannot be enforced as it is invalid;

(g) entering a final judgment on a separate paper or document under Fed. R. Civ. P. 58(a), and into the docket under Fed. R. Civ. P. 79(a);

(h) ordering the court clerk to enter a final judgment and notify the parties immediately and record such notification into the docket in compliance with Fed. R. Civ. P. 77.

(i) declaring this case exceptional and awarding Plaintiffs their costs, expenses, and attorneys' fees under 35 U.S.C. § 285; and

(j) such other and further relief as the Court may deem just, equitable and proper.

Dated: August 18, 2016

Marc D. Youngelson, Esq.
(marc@cosnerlaw.com)
Cosner Youngelson
197 Route 18 South, Suite 104
East Brunswick, NJ 08816
(732) 937-8000 (Phone)
(732) 937-5439 (Facsimile)

Of counsel:

Steven J. Moore, Esq.
(steven.moore@withersworldwide.com)
James E. Nealon, Esq.
(james.nealon@withersworldwide.com)
Withers Bergman LLP
1700 East Putnam Avenue
Greenwich, Connecticut 08630
Telephone: (203) 302-4069

Attorneys for Plaintiffs Aurobindo Pharma Limited and Aurobindo Pharma Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

I am local counsel to Plaintiffs in the above-captioned action. Pursuant to L. Civ. R. 11.2 and 40.1, and on behalf of Plaintiffs, I hereby certify that the following pending actions are related:

Astrazeneca AB et al. v. Lupin Ltd, et al., 3:15-cv-06902-MLC-TJB (counterclaim of non-infringement and invalidity of '810 patent by Lupin);

Astrazeneca AB et al. v. Zydus Pharmaceuticals (USA) Inc. et al., 3:14-cv-04782-MLC-TB (counterclaim of invalidity of '810 patent by Zydus);

Astrazeneca AB et al. v. HEC Pharm Co., LTD. et al, 3:15-cv-06025-MLC-TJB (counterclaim of non-infringement and invalidity of '810 patent by HEC Pharm Co. LTD).

Marc D. Youngelson, Esq.
(marc@cosnerlaw.com)
Cosner Youngelson
197 Route 18 South, Suite 104
East Brunswick, NJ 08816
(732) 937-8000 (Phone)
(732) 937-5439 (Facsimile)